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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,703	06/27/2000	IAN ROSS DOYLE	13704/2	9876

26646 7590 04/17/2007

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/486,703	DOYLE ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-15-07 has been entered.

Claims 51-64 are pending and under examination.

Information Disclosure Statement

The information disclosure statement filed 3-15-07 has been considered an initialed copy is enclosed.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Maintained

Claims 51-64 stand rejected under 35 U.S.C. 102(b) as being anticipated by Doyle et al (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10-18-00).

Doyle et al teach measuring SpA and SpB to screening for increases in a variety of patients including ventilated patients with no evidence of cardiorespiratory disease and screening for normal individuals (see page 152, Table 1) in sera (i.e. the instant blood) and the comparison of normal to other diseases. The "asymptomatic to lung damage or wherein the clinical diagnosis of lung damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures" is seen to meet this limitation as instantly claimed because the ventilated patients had no evidence/symptoms of cardiorespiratory disease and is also evidence of disease and "during a period in which the onset of lung damage cannot otherwise be confirmed without the aid of one or more invasive

procedures". Doyle et al teach that SP-B enters the circulation more readily than SP-A in a manner reflecting the severity of the lung injury (i.e. the instantly claimed lung damage). Doyle et al teach that when taken individually, daily changes in lung function were acutely reflected in concomitant variations in plasma SP-A, SP-B and SP-B/A. (see page 152, first full line of text). Further, the screening of "normal individuals" also meets the limitation of the claims, since these individuals would not be exhibiting a symptom specific to lung damage. The limitation of "predisposed to developing lung damage" is also met by the normal and ventilated patients because anyone alive is predisposed to developing lung damage from any of a number of causes (chemical insult, second hand smoke, pollution/ozone, trauma, etc) since they use their lungs while alive. Further, ventilated individuals are at risk from over-expansion lung injury or injury due to bacterial infection. As such, the patient populations tested by Doyle meet the limitations of the patient population claimed herein.

In contrast to Applicants' arguments Doyle et al does meets all the limitations of the claims as set forth *supra*. Applicants argue that Doyle et al does not diclsose or suggests that members of the control groups or the OD group (no evidence of cardiorespiratory disease) are "necessarily asymptomatic". This is not persuasive, normals individuals are just that, normal. If they had evidence of lung disease they are not "normal". Further, Doyle specifically characterizes the OD group as NO EVIDENCE of cardiorespiratory disease. That is they would be necessarily asymptomatic to lung damage because are they are specifically characterized as having NO EVIDENCE of cardiorespiratory disease. When you see evidence, that is a symptom. Since there was no evidence, they were no symptoms. Therefore, both these groups necessarily and inherently meet the patient population screened and would be so recognized by the skilled artisan. Although, not using the identical language, the patient populations are not distinguished nor is the method.

Claims 51-64 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Honda (Japanese Journal of Thoracic Diseases, 34 Suppl. Abstract only, December 1996; reference A11 on PTOL-1449 of 6-6-00 in view of Doyle et al (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997); reference A17 on the PTOL-1449 of 10-18-00) and Abe et al (Japanese Journal of Thoracic Diseases, 33(11):1219, Abstract only, November 1995; reference A10 on PTOL-1449 of 6-6-00).

The claims are drawn to monitoring the changes in the extent of lung damage in mammal in which there is an absence an absence of outwardly of any visible symptoms of lung damage or a method of diagnosing "early stage lung damage". Early stage lung damage as set forth in the specification specifically includes low levels of lung damage and mild but chronic lung damage (see page 9, lines 11-21).

Honda teach the measurement of surfactant proteins A and D in the sera of patients with idiopathic interstitial pneumonia (IIP) by enzyme-linked immunosorbent assay using monoclonal antibodies against humans SP-D and SP-A. Honda teaches that SP-D and SP-A increase in the sera from diseased patients. Honda teaches that the results suggest that SP-D and SP-A, can enter the blood stream easily due to injury at the alveolar-capillary membrane. Further, the serum SP-D and SP-A concentrations appeared to reflect disease activity (see abstract). The patient population having IPP have chronic lung damage and therefore meet the criteria of early stage lung damage. Honda differs by not measuring SP-B levels in serum.

Abe et al teach that the serum levels of SP-A in patients with IIP and that the SP-A levels correlated closely with the clinical course and rose significantly during exacerbations of IPP (see abstract).

Doyle et al teach measuring SpA and SpB to screening for increases in a variety of patients including ventilated patients with no evidence of cardiorespiratory disease and screening of normal individuals (see page 152, Table 1) in sera (i.e. the instant blood) and patients at risk for brohchial lavage fluid. Doyle et al teach that SP-B enters the

circulation more readily than SP-A in a manner reflecting the severity of the lung injury (i.e. the instantly claimed lung damage). Doyle et al teach that when taken individually, daily changes in lung function were acutely reflected in concomitant variations in plasma SP-A, SP-B and SP-B/A. (see page 152, first full line of text).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to screen IIP patients for lung damage at the alveolar-capillary membrane by adding the SP-B of Doyle et al to the SP-A and SP-D markers of Honda et al because Doyle teach that SP-B enters the circulation more readily than SP-A and Abe et al and Doyle et al teach that SP-A reflects the severity of the lung injury and correlates closely with disease exacerbations and it is immediately apparent that the levels can be measured/monitored to determine disease activity. As such, one skilled in the art would be able to monitor disease activity in IIP patients using the combination of SP-A, SP-B and SP-D and looking for increased levels of the markers alone or in combination and one skilled in the art would readily expect that SP-B in the serum would increase because Doyle teach that SP-B enters the circulation more readily than SP-A and Honda teaches that both SP-A and SP-D levels are increased and Abe et al teach that SP-A levels closely correlate with disease activity.

Applicants argue that Doyle fails, so does the rejection based on Doyle. This is not persuasive, Doyle et al does not fail. Applicants argue that there is no motivation to combine the references for the patient population. This is simply not persuasive, Dolye et al teach the population and include "at risk" populations and the references as combined provide motivation to monitor exacerbations of lung disease in at risk individuals or individuals with chronic disease as compared to normals and that SP-B would be a better maker because it enters the circulation more readily than SP-A. Applicant's arguments are again not persuasive and the rejections are maintained.

Status of Claims

Claims 51-64 stand rejected.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy
Primary Examiner
Art Unit 1645